REMARKS

Claims 1-32 are pending in the current application. Claims 3, 4, and 33-35 are cancelled. Claims 1, 2, 5, 7, 8, 11, 14, 15, 23, and 26-32 are amended. No new matter has been added by any of these amendments.

According to the published specification US 2006/0293340, there are two claims numbered 28. In response to the Office Action, the claim numbering refers to the correct numbering used by the Examiner. Claim 32 was amended only to reflect the correct numbering.

Applicants have carefully studied the outstanding Office Action. The present Response is intended to be fully responsive and is believed to place the application in better condition for allowance. Favorable reconsideration and allowance of this application is respectfully requested.

Claim Rejections – 35 USC § 112

The Examiner rejects claims 26-31 under 35 U.S.C. § 112, first paragraph stating that:

> the specification, while being enabling for a method of treating melanoma, does not reasonably provide enablement for a method of treating a patent having a disease characterized by excessive signaling through the MAP kinase signaling pathway. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Response

The Examiner rejects claims 26 to 31 on the basis that the specification is not enabling for the treatment of a disease characterized by excessive signaling through the MPA kinase signaling pathway. However, the Examiner also appears to acknowledge that the specification is enabling for the treatment of melanoma. Accordingly, claims 26-31 have been restricted to the treatment of melanoma. In light of these amendments, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 26-31.

The Examiner also rejects claims 1-32 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Response

With regard to point 1 at page 8 of the Office Action, the Examiner objects that in the definitions of R_1 and R_2 the terms "phenyl radical" and "heteroaryl radical" are not clear. Accordingly, the claims have been amended to clarify the definitions of R_1 and R_2 as follows.

> "R_1 is an unsubstituted phenyl radical and lower alkoxy-substituted phenyl, wherein the lower alkoxy substituent is at the position meta or para to the bond to the pyrimidine ring, or a heteroaryl radical selected from a thiazolyl, pyrazinyl, pyrimidinyl or 6-substituted-3-pyridyl radical"
>
> "R_2 is a phenyl radical that is substituted in at least the 3-position by fluorine, halo-lower alkyl, halo-lower alkoxy, or halo-lower alkylthio"

Support for the amendments regarding R_1 may be found at paragraphs [0022] and [0029] of the published specification (US 2006/0293340) of the present application. Support for the amendments regarding R_2 may be found at paragraphs [0024] of the published specification of the present invention as well as claim 4 as originally presented. In view of these amendments, claims 3 and 4 have been cancelled.

With regard to point 2 at page 8 of the Office Action, the examiner objects that there is insufficient antecedent basis for the recitation in claim 3 "wherein R2 is phenyl that is substituted in at least the 3-position by halogen, ..." Claim 3 has been cancelled and claim 1 now reflects that the phenyl radical presented by R_2 is substituted.

With regard to point 3 at page 9 of the Office Action, the examiner objects that in claim 7 the definition "C" for A1, A2 and A3 leaves two of the ring members with an open valency and that "it is not clear what is intended to be substituted on this ring." Applicants thank Examiner for pointing out this inadvertent error, which has now been corrected with the amendments presented to claim 7 wherein the references to "C" have been amended to "CH" so as to provide the correct valency when A1, A2 or A3 is not N.

With regard to point 4 at page 9 of the Office Action, Applicants again thank Examiner for pointing out the inadvertent error with regard to the term "R_2." Claim 8 has been amended to reflect the proper term "R_4."

Finally, with regard to point 5 at page 9 of the Office Action, Applicants again thank for pointing out this inadvertent error as to the term "phenyl" in claim 11. Indeed, claim 11 is intended to recite the preferred limitation on the subject matter of claim 10 in which R4 is halo-lower alkyl, etc. and not *phenyl* halo-lower alkyl. Therefore, in amended claim 11, the term "phenyl" has been deleted.

In light of the above remarks and amendments to the claims rejected in points 1-5 of the Office Action at pages 8-9, Applicants respectfully request that the rejection of claims 1-32 under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

Claim Rejections – 35 USC § 102

1) Claims 1, 2, 5, 26, and 32

The Examiner has rejected claims 1, 2, 5, 26, and 32 under 35 U.S.C. § 102(b) as being anticipated by Zimmermann, US Patent 5,521,184 (hereinafter "Zimmermann"). Applicants respectfully traverse this rejection for the following reasons.

Original claim 1 has been amended by the incorporation of the features of original claim 4. Thus, the definition of claim 1 now does not include compounds in which R2 is an alkyl substituted phenyl radical. Zimmerman, in examples 17, 21, 22, 24 and 25, as identified by the Examiner, discloses N-phenyl-2-pyrimidine-amine compounds wherein the phenyl moiety is substituted by an alkyl e.g. methyl, substituted benzoyl amido group. Such compounds are not within the scope of our revised claim 1 and therefore claim 1 cannot be said to be anticipated by Zimmerman. Consequently, Applicants respectfully request that the rejection that the rejection of claims 1, 2, 5, 26, and 32 under 35 U.S.C. § 102(b) in light of Zimmermann be reconsidered and withdrawn.

2) Claims 1-3, 5, 26, and 32

The Examiner has rejected claims 1-3, 5, 26, and 32 under 35 U.S.C. § 102(b) as being anticipated by Buerger et al., WO 2002/022597 (hereinafter "Buerger"). Applicants respectfully traverse this rejection for the following reasons.

As previously mentioned, claim 1 has now been amended by the incorporation of the features of claim 4, which are not objected to by the examiner. Thus, the amended claims as presented herein no longer read on reference disclosed compounds. Consequently, Applicants respectfully request that the rejection that the rejection of claims 1-3, 5, 26, and 32 under 35 U.S.C. § 102(b) in light of Buerger be reconsidered and withdrawn.

3) Claims 1-3, 5, and 26

The Examiner has rejected claims 1-3, 5, and 26 under 102(a), (b), and/or (e) as being anticipated by Stein-Gerlach et al., WO 2002/93164 (hereinafter "Stein-Gerlach"). Applicants respectfully traverse this rejection for the following reasons.

As previously mentioned, claim 1 has now been amended by the incorporation of the features of claim 4, which are not objected to by the examiner. Thus, the amended claims as presented herein no longer read on reference disclosed compounds. Consequently, Applicants respectfully request that the rejection that the rejection of claims 1-3, 5, and 26 under 35 U.S.C. § 102(b) in light of Stein-Gerlach be reconsidered and withdrawn.

Claim Rejections – 35 USC § 103

Claims 1-32

The Examiner has rejected claims 1-32 under 35 U.S.C. § 103(a) as being obvious over Buerger. Applicants respectfully traverse this rejection for the following reasons.

Buerger discloses a wide generic group of pyrimidine-2-amine compounds. However, the compounds exemplified by Buerger only include compounds in which the pyrimidine is substituted by an unsubstituted pyridine. It should be noted that the amendments to claim 1 restrict the claims of the present application to compounds in which, when R1 of formula I is a pyridine moiety, it is specifically a 6-substituted-3-pyridyl radical. Buerger only teaches unsubstituted pyridines and therefore cannot be said to teach towards this specific substitution pattern required for the compounds of the present invention as defined by the revised claim 1.

Claims 1-31

The Examiner has rejected claims 1-31 under 35 U.S.C. § 103(a) as being obvious over Stein-Gerlach. Applicants respectfully traverse this rejection for the following reasons.

Even the broad generic disclosure of Gerlach et al. in formula I is to compounds in which the pyridyl moiety attached to the pyrimidine group is unsubstituted. As discussed in point 1 above, the present application is now limited to the case where the pyridine moiety it is a 6-substituted-3-pyridyl radical. Therefore, as with Buerger, the art is clearly teaching that the pyridine moiety should be unsubstituted and is therefore teaching away from the invention as defined by revised claim 1 herein.

Double Patenting Rejections

The Examiner provisionally rejects claims 1-12, 18, 19, and 26-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over pending claims 1-6, 8, and 11 of copending Application No. 10/528,913.

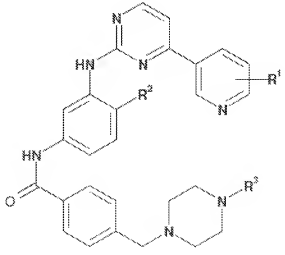
Response

Applicants respectfully traverse this rejection, as claim 1 of this co-pending application, to which the Examiner directs Applicants, as originally submitted and allowed, defines compounds in which the pyridine moiety is unsubstituted. In contrast, the claims in the present application recite to compounds in which, when a pyridine moiety is present, the pyridine is a 6-substituted-3-pyridyl radical. Thus, for at least this reason, the compounds are patentably distinct from each other. Consequently, Applicants respectfully request reconsideration and withdrawal of the double patenting rejection in light of copending Application No. 10/528,913.

The Examiner further provisionally rejects claims 1-12, 18, 19, and 26-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over pending claims 21, 30, 32, 36, and 44 of copending Application No. 10/502,291.

Response

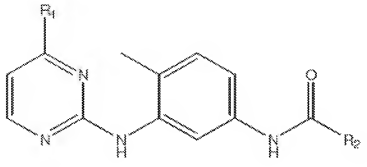
Applicants also respectfully traverse this rejection. Claim 21 of this co-pending application, now issued US patent no. 7,557,105, claims N-phenyl-2-pyrimidine amine derivatives of formula I:



I

As seen from the structure above, the structure includes, *inter alia*, a benzyl piperazinyl group.

As amended, claim 1 of the present application defines N-phenyl-2-pyrimidine amine derivatives of formula (I):



(I)

in which R^2 is a phenyl and not a benzyl radical and in which R^2 is substituted in at least the 3-position by fluorine, halo-lower alkyl, halo-lower alkoxy, or halo-lower alkylthio, regardless of any other substitution on the phenyl ring. For at least this reason, the compounds of the revised claim 1 and its dependent claims are patentably distinct from those cited in US 7,557,105. Consequently, Applicants respectfully request reconsideration and withdrawal of the double patenting rejection in light of copending Application No. 10/502,291.

CONCLUSION

An Office Action on the merits is now respectfully awaited. If there are any outstanding issues that the Examiner feels may be resolved by way of a telephone conference, the Examiner is cordially invited to contact Colin P. Cahoon or Celina Diaz at 972.367.2001.

The Commissioner is hereby authorized to charge any additional payments that may be due or credit any overpayment to Deposit Account No. 50-0392.

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Respectfully submitted,

/CMD 61132/

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